

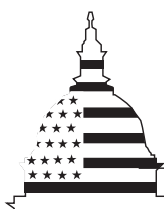
GAO

Report to the Chairman of the
Subcommittee on National Security,
Veterans Affairs and International
Relations, Committee on Government
Reform, House of Representatives

March 2001

COMBATING TERRORISM

Accountability Over Medical Supplies Needs Further Improvement



G A O

Accountability * Integrity * Reliability

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Abstract This report responds to your request that we follow up on the status of the corrective actions taken by the responsible agencies to address the internal control weaknesses and recommendations previously reported in October 1999 1 that could affect the United States ability to effectively respond to chemical or biological terrorist incidents. This ability is dependent, among other things, on the plans, methods, and procedures used to ensure that the medical supplies designated for this purpose are current, accounted for, and ready for use. The Presidents fiscal year 2001 budget proposed spending about \$11.3 billion to combat terrorism. Among the resources the federal government is devoting to combating chemical and biological terrorism is funding to develop and maintain a national stockpile 2 of pharmaceutical and medical supplies that can be used to treat civilian and military victims of chemical and biological terrorist acts.		
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United States General Accounting Office
Washington, D.C. 20548

March 30, 2001

The Honorable Christopher Shays
Chairman
Subcommittee on National Security, Veterans Affairs
and International Relations
Committee on Government Reform
House of Representatives

Dear Mr. Chairman:

This report responds to your request that we follow up on the status of the corrective actions taken by the responsible agencies to address the internal control weaknesses and recommendations previously reported in October 1999¹ that could affect the United States' ability to effectively respond to chemical or biological terrorist incidents. This ability is dependent, among other things, on the plans, methods, and procedures used to ensure that the medical supplies designated for this purpose are current, accounted for, and ready for use. The President's fiscal year 2001 budget proposed spending about \$11.3 billion to combat terrorism. Among the resources the federal government is devoting to combating chemical and biological terrorism is funding to develop and maintain a national stockpile² of pharmaceutical and medical supplies that can be used to treat civilian and military victims of chemical and biological terrorist acts.

¹*Combating Terrorism: Chemical and Biological Medical Supplies Are Poorly Managed* (GAO/HEHS/AIMD-00-36, October 29, 1999).

²Marine Corps Chemical Biological Incident Response Force (CBIRF) officials refer to the medical supplies they maintain as a working stock. To simplify our presentation, we refer to CBIRF's medical supplies as a stockpile.

In response to your request, our objective was to follow up on actions taken to address our recommendations that the Department of Health and Human Services' (HHS) Office of Emergency Preparedness (OEP) and Centers for Disease Control and Prevention (CDC),³ the Department of Veterans Affairs (VA),⁴ and U.S. Marine Corps Chemical Biological Incident Response Force (CBIRF) establish sufficient systems of internal control over chemical and biological pharmaceutical and medical supplies by (1) conducting risk assessments, (2) arranging for periodic, independent inventories of the stockpiles, (3) implementing a tracking system that retains complete documentation for all supplies ordered, received, and destroyed, and (4) rotating stock properly.

Results in Brief

OEP, VA, CDC, and CBIRF have made significant progress toward implementing the recommendations made in our October 1999 report to address identified internal control weaknesses. Management at each of the responsible agencies has given priority to and placed emphasis on strengthening internal controls over the stockpiles. As a result, corrective actions have reduced inventory discrepancy rates and improved accountability. At the same time, we found that in all the areas associated with our prior recommendations, additional steps can be taken to ensure that pharmaceutical and medical supplies that can be used to treat victims of chemical and biological terrorist incidents are current, accounted for, and readily available for use.

³At the time of our prior review, CDC was in the initial start-up phase of its National Pharmaceutical Stockpile Program; therefore, we did not assess its internal controls. However, we made recommendations to CDC, along with the other responsible agencies, to consider in implementing its program.

⁴Under a memorandum of agreement with OEP, VA is responsible for the purchase, storage, quality control, maintenance, exercise, and contingent deployment of pharmaceutical and medical supplies. Also, VA is a purchasing and contracting agent for CDC's National Pharmaceutical Stockpile Program. VA does not maintain its own stockpile for use in the event of a terrorist incident.

Although OEP, VA, CDC, and CBIRF conducted risk assessments since our last report, we found instances where the risk assessments were not sufficiently comprehensive or where actions identified to mitigate risks had not yet been implemented. For example, CDC's risk assessment did not adequately address risks specific to the development phase of the National Pharmaceutical Stockpile Program (NPSP), in which CDC is partnering⁵ with various contractors and subcontractors to manage and store its medical supplies. Although it placed supplies at five of its six locations, at the end of our fieldwork CDC had not finalized agreements with its partners covering key responsibilities. Without such agreements in place, there is an increased risk that mission critical activities may not be carried out.

In other instances, actions taken to mitigate risks were not yet fully implemented. For example, while CDC's risk assessment identified theft as a risk, and its handbook specified erecting a fence as a deterrent, stockpiles were placed at four locations prior to erecting the fences. In another case, OEP had identified the sensitivity of the medical supplies to extreme temperatures as a risk that could affect drug stability and potency and had subsequently installed temperature monitoring devices. However, during one of our site visits we noted that the monitor registered nine degrees higher than the maximum temperature recommended by the manufacturers. In April 2001, OEP plans to replace affected stock and relocate the stockpile, which constitutes over 20 percent of OEP's total stock. In the interim, the affected items may not be effective, should an incident occur.

⁵Partnering, in the context of this report, is the association of two or more entities in a business relationship.

Each of the responsible agencies has conducted various periodic inventory counts and, as a result, discrepancies between inventory records and physical inventories have significantly decreased. However, OEP has not yet provided to VA, nor has VA developed written guidance stipulating the frequency of inventory counts or acceptable discrepancy rates. In addition, we found instances where certain medical supplies on hand at CBIRF fell short of those specified in the Commanding Officer's (CO's) medical allowance list, which provides an interim baseline for medical supplies needed. CBIRF does not plan to order additional supplies to conform to this list, because the Marine Corps System Command (MARCORSYSCOM) has provided a specific authorized medical allowance list (AMAL),⁶ which supercedes the CO's list. MARCORSYSCOM is in the process of programming funding and developing the fielding plan for CBIRF to follow in adjusting its stock levels to conform to the AMAL. Further, OEP does not have an updated inventory requirements list to reflect recent changes in the composition of its stockpile. Unless OEP updates its inventory requirements list and conducts periodic inventories in the future, OEP will not be able to determine whether it has the necessary supplies to meet its mission or identify patterns of shortages, overages, or other discrepancies and take timely action.

Although inventory discrepancy rates have significantly improved since our prior report, the current inventory tracking systems used by OEP, VA, CDC, and CBIRF lack certain fundamental information as previously reported. For example, the agencies' systems still do not record and track all activity throughout the life cycle of each product stocked. The agencies are taking steps to replace their current systems with ones that are capable of tracking pharmaceutical and medical supplies from the time an order is placed until the item is consumed or otherwise disposed of. At the completion of our fieldwork, CDC was reviewing vendor proposals for a new system. OEP expects to rely on the results of CDC's review and use the same system as that selected by CDC. The Marine Corps has developed a new inventory system, ATLAS II+, that it expects to implement at CBIRF by June 2001.

⁶Authorized Medical Allowance List (AMAL) sets the minimum level of medical supplies to be kept on hand to meet mission needs.

In determining whether OEP, VA, CDC, and CBIRF are properly rotating pharmaceutical and medical supplies in a timely manner, we inspected the agencies' inventories and records and found no expired items in OEP's and CDC's stockpiles. This was a marked improvement for OEP, since we had found expired items in its active inventory in our prior review. For CBIRF, we identified 161 expired items on hand during our October 2000 inventory count, but this represented less than 1 percent of its inventory. However, these expired items included controlled substances such as morphine sulfate, acetaminophen and codeine phosphate, and midazolam⁷ that had expired but not been replaced. Neglecting to remove and replace expired items – especially controlled substances – promptly, increases the risk of an inadequate supply of effective items being on hand and available for deployment with CBIRF should a terrorist incident occur.

We are making 13 new recommendations to the responsible agencies to (1) minimize the risks associated with partnering with private companies and other entities, (2) improve accountability over pharmaceutical and medical supplies, and (3) ensure the effectiveness of supplies on hand.

We obtained written comments on a draft of this report from HHS, VA, and the Department of Defense (DOD). The agencies concurred with the overall conclusion of the report and 12 of 13 recommendations. HHS did not agree with our recommendation that CDC install fencing prior to placing inventories at storage locations. Subsequently, we modified our recommendation as follows: "To the extent practical, install proper fencing prior to placing inventories at storage locations." In addition, we clarified the potential impact of certain other issues based on agency comments. Also, in their comments, the agencies described several actions that they are taking to strengthen management controls in response to our recommendations.

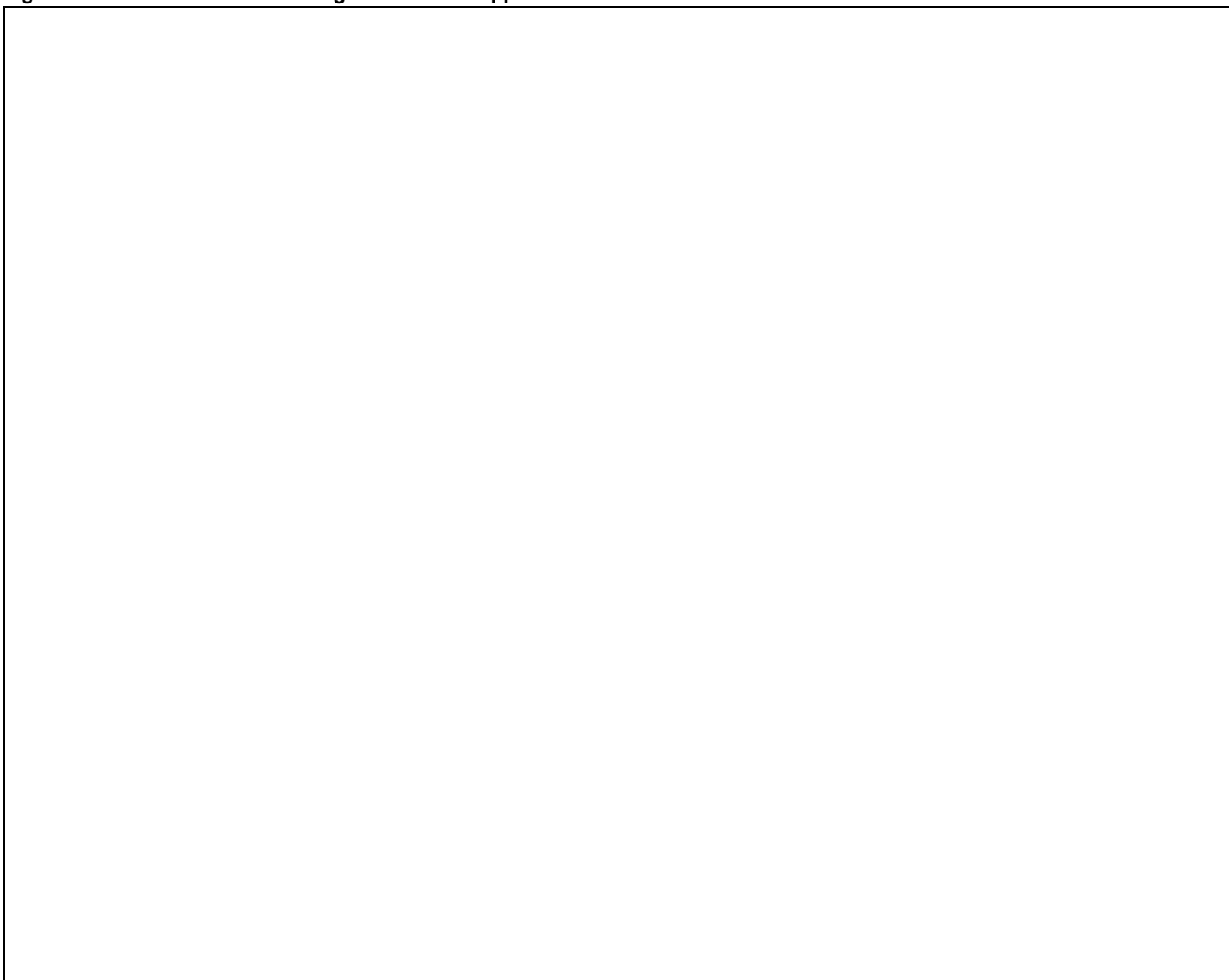
Background

The United States has established a national policy for combating chemical and biological terrorism and managing the consequences of terrorist attacks. In the event of a domestic chemical or biological terrorist incident, local and state governments would be the first to respond in assisting civilian victims. If the consequences of such an incident overwhelmed state and local capabilities, federal assistance could be given to support their

⁷See glossary for a definition of pharmaceuticals and medical supplies.

efforts. Critical to that assistance are the chemical and biological medical supplies maintained by OEP, VA, CDC, and CBIRF. A description of the support these agencies could provide is described below and depicted in figure 1.

Figure 1: U.S. Chemical and Biological Medical Supplies Used to Combat Terrorism



Source: GAO analysis based on our review of HHS's and CDC's operating plans and CBIRF documents.

If a national emergency has been declared, the Federal Emergency Management Agency (FEMA) is responsible for managing the support provided by other federal agencies and coordinating response activities with state and local authorities. FEMA coordinates the federal response through the Federal Response Plan and the Terrorism Incident Annex, which establishes a general concept of operations for the federal response to a terrorist incident. FEMA, through the Federal Response Plan, has designated HHS as the lead agency to coordinate medical assistance in the event of a federally declared natural or man-made disaster, including chemical or biological terrorist incidents. Within HHS, OEP is responsible for implementing and coordinating this medical assistance and has, among other efforts, established four National Medical Response Teams (NMRTs) in different regions of the country and staffed the teams with specially trained doctors, nurses, other health care providers, and emergency personnel whose mission is to decontaminate and/or treat victims of a terrorist attack. Under a memorandum of agreement between VA and OEP, VA maintains a medical stockpile containing antidotes, antibiotics, and medical supplies for responding to chemical terrorist attacks at locations near each team. OEP also maintains one smaller stockpile that contains only antidotes for chemical incidents. This stockpile can be loaned to local governments or predeployed for special events, such as the Olympic Games.

For the past 26 years, among other duties, CDC has maintained the nation's stockpile of the smallpox vaccine. In fiscal year 1999, the Congress appropriated \$51 million to CDC to establish and implement the NPSP.⁸ CDC received an additional \$52 million of stockpile funds in each of the following 2 fiscal years. The program is responsible for establishing a pharmaceutical and medical stockpile to counter the potential threats to civilian populations of injury or disease due to chemical or biological terrorism. Within this charge, the program's primary focus is on biological terrorist attacks. Since November 1999, CDC has been building the National Pharmaceutical Stockpile (NPS), which is comprised of two types of inventories. The first is a rapid response inventory of pharmaceutical and medical supplies that can be positioned at any location in the nation within 12 hours of a federal decision to deploy assets, referred to as 12-hour push packages by CDC. The second is a larger stock of supplies that can be deployed within 24 to 36 hours of notification, and can be tailored to address a particular type of incident and augment the rapid response inventory, referred to as vendor managed inventories.⁹ In the event of an incident, its stock is shipped in bulk and is accompanied by CDC technical advisors who assist and advise state and local officials in organizing the bulk stock medications into individual doses and implement plans to distribute and dispense the medication. VA acts as a purchasing agent for NPSP medical materiel, providing CDC access to VA's purchasing experience and the ability to purchase medical supplies at significant discounts.

CBIRF, created in April 1996 by the Commandant of the Marine Corps, is an incident response force and maintains a working stock of medical material to provide emergency medical care and stabilization of injured CBIRF personnel and a limited number of other casualties. CBIRF is also trained and equipped to provide for the detection and identification of chemical agents as well as for casualty extraction and decontamination. Thus, it should be noted that the purpose of the medical supplies managed by CBIRF is fundamentally different from that of OEP's and CDC's programs in that CBIRF stocks chemical antidotes and medical supplies in only those amounts sufficient to treat team members and a limited number of civilian

⁸Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (P.L. 105-277).

⁹Vendor managed inventories are carried on the manufacturers' inventory records as either "government owned" or "government reserved" and may be rotated with the vendor's normal operating stock in order to assure freshness.

victims. Accordingly, its stock of antidotes and medical supplies is much smaller than that of OEP and CDC.

Scope and Methodology

To determine the status of corrective actions taken to address our prior recommendations, we interviewed responsible agency officials, reviewed agency documentation, and observed agency operations and facilities at the OEP, VA, CDC, and CBIRF sites that currently store medical supplies. We also performed a 100-percent count of the CBIRF medical supplies with CBIRF assistance and observed and participated in counts of OEP and CDC medical supplies with OEP, VA, and CDC officials. The scope of our work spanned from the point that OEP, CDC, and CBIRF identified medical supplies to be included in their inventories to the point that the medical supplies would be released from the storage sites in response to a terrorist incident. Our review did not include an analysis of (1) how these stockpiles fit into national counterterrorism plans, (2) the concept of operations for the use of these stockpiles, or (3) whether these stockpiles contain the appropriate medications. We also did not review management controls over medical supplies after the point that they would be deployed for a terrorist incident. These issues are the subject of several recently published GAO studies.¹⁰ We conducted our review from August 2000 through December 2000 in accordance with generally accepted government auditing standards. See appendix I for a full description of our objective, scope and methodology.

Agencies Performed Risk Assessments but Did Not Recognize or Mitigate All Relevant Risks

In October 1999, we reported that neither OEP, VA, nor CBIRF had determined the risks that face their stockpiles, assessed the likelihood of each risk's occurrence, and established plans to detect or mitigate the risks. Since then these agencies have completed risk assessments that identify risks and actions to mitigate those risks. CBIRF not only completed a risk assessment, including a physical security analysis, but it also implemented controls to mitigate risks identified in its assessment. However, for CDC and OEP we found instances where the risk assessments were not sufficiently comprehensive or where actions identified to mitigate risks had

¹⁰ *Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives* (GAO/T-NSIAD-99-112, March 16, 1999), *Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks* (GAO/NSIAD-99-163, September 7, 1999), and *Combating Terrorism: Linking Threats to Strategies and Resources* (GAO/T-NSIAD-00-218, July 26, 2000).

not been fully implemented. For example, CDC and OEP are partnering with various federal and commercial entities for the storage, management, and transporting of their pharmaceutical and medical supplies. As of the completion of our fieldwork, neither agency had considered all of the risks posed by delegating key responsibilities to other entities, nor had they taken all the necessary steps to mitigate those risks.

The federal government's standards for internal control¹¹ state that internal control should provide for an assessment of the risks the agency faces from both external and internal sources. According to these standards, agencies should conduct risk assessments to (1) identify all potential internal and external risks, (2) rank the risks by assessing their likelihood and their effect on achieving mission objectives, and (3) act to mitigate those risks. Until each agency develops and fully implements comprehensive risk assessments and plans for mitigating those risks, each will have limited assurance that mission critical activities will be carried out as contemplated.

Risk Assessments Did Not Recognize All Risks Inherent in Partnering With Other Entities

CDC completed a risk/benefit assessment in February 2000 that identified and analyzed the significance of the hazards and risks facing the NPS as a basis for establishing actions needed to mitigate those risks. However, CDC did not consider risks that might threaten its mission as a result of partnering with other entities, especially during the start-up phase of the program, which began in January 1999 and is still ongoing.

In November 1999, CDC partnered with VA to serve as a purchasing and contracting agent for the NPSP. The partnership allowed CDC to take advantage of VA's contracting experience and purchasing power by having VA purchase supplies at significant discounts, thereby achieving significant cost savings that could benefit other areas of the program. VA received initial funds from CDC and began purchasing materiel for the rapid response inventory in November 1999.

Once items were purchased, VA configured the supplies to establish eight rapid response inventories, also referred to as "push packages." At the end of our fieldwork, CDC had placed six of its rapid response inventories at five of six permanent sites managed by a wholesale distributor or other

¹¹*Internal Control: Standards for Internal Control in the Federal Government* (GAO/AIMD-00-21.3.1, November 1999).

external parties, as illustrated in figure 2, prior to obtaining signed agreements with its proposed partners for the storage, management, and transporting of stock in the event of an incident. CDC placed three of the inventories with a wholesale distributor, which CDC anticipates will also manage the supplies stored at these facilities. Three of the inventories were placed at two privately owned warehouses. CDC anticipates the wholesale distributor will manage the stockpiles located at these warehouses. The remaining two inventories have not been placed at permanent sites, but CDC expects to place one at a private warehouse, which will be managed by the wholesale distributor, and the other at a federal facility, which will be managed by CDC with assistance from a part-time employee at the site.

Figure 2: CDC Operations



Source: GAO analysis based on the review of CDC's NPSP Operating Plan.

In November 2000, CDC developed and issued standard operating procedures in the form of a handbook to the managers of the wholesale distributor, which is responsible for storing and managing CDC's supplies stored at its facilities and managing those stored at the private warehouses. CDC also issued its handbook to the managers at the private warehouses. There is not, however, a written agreement between CDC, VA, and the wholesale distributor that covers all the wholesale distributor's responsibilities. While the handbook provides guidance for storing and managing CDC's supplies, without written agreements between CDC and its partners covering key responsibilities, there is a greater risk that those procedures will not be carried out.

In addition, the handbook does not fully address policies, procedures, and control activities that apply to the private warehouses that are responsible for storing, but not managing, the supplies. For example, the handbook does not provide guidelines to the private warehouses for granting access to the stockpiles for rotation and management of the stock by the wholesale distributor or part-time employee at the federal facility. Likewise, the handbook does not provide an interim plan that addresses access and security controls or rotation of expiring stock by others. Without adequate procedures in place to guide control activities, management cannot be assured that responsibilities are clearly communicated to warehouse personnel entrusted with NPS materiel, raising the risk that unauthorized access to the supplies will be gained or that stock will not be timely and consistently rotated. In addition, while CDC officials told us that they plan to use private air cargo and land transport companies to transport the stockpiles in the event of a terrorist incident, as of the completion of our fieldwork, there were no standard operating procedures or signed agreements to cover these arrangements.

OEP completed its risk assessment in December 2000. However, it did not recognize all the risks associated with delegating responsibility for the storage and management of its stockpiles to VA. Between April and December 2000, OEP and VA jointly drafted both national and local operating plans¹² in accordance with their memorandum of agreement.

¹²The OEP/VA national plan addresses the responsibilities, concept of operations and procedures for the procurement, storage, management and deployment of OEP's stockpiles. The local plans address key responsibilities of VA personnel as it relates to each storage site, for example the amount of space and level of security to be provided and procedures to be followed for the controlled release of supplies when federal assistance is requested in response to a chemical or biological terrorist incident.

However, these plans had not been finalized or approved by OEP as of the end of our fieldwork. Although the draft local operating plans were provided to the VA locations storing the stockpiles, security personnel at two of the locations were unable to provide us with a copy of the draft plan or associated training materials. In addition, they could not demonstrate that the plan had been communicated to them and was readily available to use in a test or an actual terrorist incident.

Actions Identified by CDC and OEP to Mitigate Risks Were Not Fully Implemented

For OEP and CDC, we also noted instances where risks had been appropriately identified, but plans for mitigating these risks were not fully implemented. For example, CDC's risk assessment identified physical security as a risk, and its handbook specified a number of actions to mitigate the risks including the use of alarms, video devices, and chain link fences of at least 10 feet with lock-secured gates around the NPS inventory. However, the stockpiles were placed at four locations prior to erecting fences to segregate the CDC stock from that of the wholesale distributor or others sharing adjacent warehouse space. Placing the stockpiles at storage facilities prior to erecting fencing exposes the supplies to unauthorized access. For up to 3-1/2 months, the supplies were not segregated by fencing at four of the facilities and management was unable to limit or control access to the supplies, as prescribed in CDC's standard operating procedures.

OEP also prepared a risk assessment that identified the risks to its program, determined the probability of occurrence, and established plans for mitigating the risks. However, some plans were not fully implemented by the end of our fieldwork. For example, one of the risks identified in the assessment was the sensitivity of the medical supplies to extreme temperatures that could damage the drug or medical item. According to OEP's risk assessment, should this occur, the items affected were to be replaced.

Since our prior study, OEP installed temperature monitoring devices at each of the locations to monitor temperature minimums and maximums during the period between site visits. We noted during our site visit to its central location that the temperature monitoring device at the facility registered 95 degrees Fahrenheit, and that manufacturers of some pharmaceuticals stored in this facility warrant their products only if the items are stored at temperatures not over 86 degrees. While the facility is heated in the winter, it lacks air conditioning. This facility houses over 20 percent of OEP's stock of pharmaceutical and medical supplies, most of

which is not refrigerated. Pharmaceuticals subjected to the extreme temperatures included diazepam, atropine, and ciprofloxacin. There was no way of knowing how often or for how long the temperature exceeded the maximum over the summer at this location because these devices cannot measure the frequency or duration in which appropriate temperatures for storage of pharmaceuticals were exceeded. Such information would be necessary to determine whether the subjected pharmaceutical and medical supplies are at risk of deterioration due to exposure to extreme temperatures.

Subjecting pharmaceuticals to excessive temperatures can affect the stability and utility of the items. According to VA's Handbook, items exposed to extreme temperatures are to be inspected by qualified VA personnel, local health officials, or if necessary, the Food and Drug Administration (FDA). The handbook states that stock confirmed unfit for use should be dropped from inventory records and physically disposed of as soon as possible. However, in this case such procedures were not followed. Rather, OEP officials told us that they planned to relocate the stockpile to an environmentally controlled facility in April 2001, and replace the affected goods at that time. In the meantime, these items may not be effective in the event of a terrorist incident.

In the course of our review, we also found weaknesses in OEP's physical security over controlled substances at its central location. During our November site visit, we noted that the OEP storage cages at this location did not comply with Drug Enforcement Administration (DEA) regulations for the storage of controlled substances. The storage cage within the warehouse facility used to store OEP medical supplies, including controlled substances, was not equipped with an alarm system which upon unauthorized entry would transmit a signal to VA security or the local police agency, as required by DEA regulations.¹³ OEP officials told us that they do not plan to add an alarm system at this location because of their plans to move these supplies to the new facility in April 2001. They stated that the new facility will comply with DEA regulations. In the meantime, inadequate physical safeguards raise the risk that the controlled substances could be stolen and the theft not promptly detected.

¹³21 CFR 1301.72 (b)(4)(v), (2000).

Inventory Accuracy Improved but Additional Actions Are Needed

We previously reported large discrepancies between data recorded in CBIRF's and OEP's inventory systems and physical counts of their inventories. In addition, during our prior review, we noted that while OEP had identified and prepared a list of the minimum pharmaceuticals and medical supplies needed to carry out its mission (requirements list), CBIRF had not. In our current review, we noted that while discrepancies still existed, the accuracy of both CBIRF and OEP inventory records had improved significantly. However, OEP lacked certain detailed written inventory procedures necessary to help ensure overall reliability of inventory records. We also found in our current review that CBIRF had developed a requirements list; however, it did not have on hand all items included in the list. Also, OEP had not updated its requirements list for significant increases to its stockpile. These issues need to be addressed in order to ensure the readiness of the inventory in the event of a chemical or biological incident.

Since our October 1999 report, CDC has developed an inventory requirements list and is using the list as a basis for making inventory purchases to establish the NPS. It has also begun performing periodic inventory counts, and as of the end of our fieldwork, no unresolved discrepancies between medical supplies on hand and system data had been identified.

Periodic Inventories Reduced Discrepancy Rates

Since our inventory counts of CBIRF's medical supplies in 1999, the discrepancy rate has declined from 26 percent to approximately 10 percent. While this is a significant improvement, we found during our most recent counts that the inventory system still had inaccurate or incomplete data. We found discrepancies in quantities, expiration dates, and lot numbers. Approximately 6.7 percent of the discrepancies we found were quantity discrepancies and approximately 3.3 percent were discrepancies in the lot numbers or expiration dates. It is important to note, however, that no discrepancies were found between the records for controlled substances and data from the physical inventory of controlled substances. CBIRF had no official explanation for the noted variances and identified human error as the likely cause.

In response to our prior report, VA began performing quarterly inventory counts on behalf of OEP in April 2000. As a result, the inventory discrepancy rate declined from approximately 11 percent, as previously reported, to less than 1 percent in November 2000. In addition to current inventory items on hand for immediate deployment in response to an incident, VA was also holding certain expired controlled substances for OEP, pending approval by FDA to extend the shelf life of these items. As of December 2000, VA was holding 17,897 expired items for OEP for this purpose. When we counted these expired items and compared the results to VA's inventory records, we found that approximately 5 percent of the expired items were not listed in the system. DEA regulations require that a complete and accurate record of all controlled substances on hand shall be maintained in written form.¹⁴ VA officials told us that they attribute the higher discrepancy rate for these expired items to less frequent inventory counts and a lack of periodic reconciliation of system data to what is on hand.

While OEP's overall discrepancy rate has significantly improved, it has not provided, nor has VA established, written guidance stipulating acceptable discrepancy rates or the frequency of inventory counts. Sustained progress is dependent upon setting goals against which performance can be measured and conducting periodic inventories. Without these, OEP will not be able to measure improvement or determine the reliability of inventory records.

Since CDC is in the process of establishing the NPS, it just recently began performing quarterly cyclical inventory counts, as well as quality assurance reviews. From September through November 2000, we observed and participated in CDC's quarterly inventory counts at three sites. To date, no unresolved discrepancies have been identified between the quantities of supplies recorded in the inventory system and the physical counts.

Inventory Requirement Levels Were Not Always Provided or Followed

We previously reported that OEP had a list of pharmaceutical and medical supplies and quantities required to meet its mission. In fiscal year 1999, OEP authorized the purchase of about \$1.6 million in chemical antidotes to increase the total number of victims that could be treated in a chemical incident from 8,000 to 20,000. At the end of our fieldwork, OEP had not yet updated and issued an official inventory requirements list to reflect recent

¹⁴21 CFR 1304.11, (2000).

increases in its stockpile. As a result, OEP cannot be assured that it has the right composition and quantity of medical supplies readily available, and VA has no official baseline for maintaining the requisite materiel on hand to support OEP's mission.

In our October 1999 report we also noted that CBIRF did not have an approved list of what items should be in its inventory. In May 2000, CBIRF established a CO's Medical Allowance List. The allowance list, updated in December 2000, provided an interim baseline for the medical supplies that CBIRF officials determined were needed to meet the agency's mission until the MARCORSYSCOM issued a CBIRF specific AMAL. Subsequently, CBIRF officials told us that MARCORSYSCOM had approved the AMAL, but it had not yet provided the funding nor developed the fielding plan for adjusting the stock to conform to the AMAL as of the end of our fieldwork. When we did our inventory count in October 2000, we noted that CBIRF did not have on hand all of the medical supplies included in its May 2000 CO list. For example, the CO list called for 406 intravenous sets but only 163 were on hand. Also, the CO list called for stocking 394 oropharyngeal airways, but only 166 were on hand. CBIRF officials told us that they do not plan to order additional supplies until MARCORSYSCOM provides funding and develops a fielding plan for CBIRF to follow in adjusting its inventory of medical supplies, because they want to avoid potentially overstocking supplies. As such, the CO stated that once the MARCORSYSCOM programs funds and develops the fielding plan, CBIRF will adjust its physical stock to conform to the AMAL.

We found that CDC had developed internal guidelines for the composition and stock levels of medical supplies purchased to establish the NPS, particularly the rapid response inventory. CDC developed its initial inventories pursuant to guidance contained in the 1999 HHS Operating Plan for Bioterrorism Initiative, with input from the NPSP Working Group, which consisted of external experts in emergency response/medicine, public health, pharmacy and logistics management. CDC later established a medical review panel of internal subject-matter experts in infectious disease, emergency response/medicine, public health, medical management and toxicology, to review, validate and make recommendations regarding the NPS composition and stock levels on an as needed basis. We concluded that CDC followed its internal guidelines for establishing the composition and stock levels of its medical supplies and is using its requirements list to guide its purchase of supplies for the NPS. As of the end of our fieldwork, CDC had filled approximately 47 percent of its rapid response inventory requirement, based on the requirements list.

However, the requirements for the vendor-managed inventory had not been filled, since CDC had just begun negotiations and contracting with vendors for this inventory.

Current Tracking Systems Do Not Record Inventory Activity Over the Life Cycle of the Supplies

We previously reported that the responsible agencies' inventory systems did not adequately track inventory items and recommended that they implement tracking systems that retain complete documentation for all supplies that have been ordered, received, and destroyed. The current inventory systems used by OEP, VA, CDC, and CBIRF still lack certain fundamental information, which impedes their ability to comprehensively track their pharmaceutical and medical supplies.

Maintaining accountability over inventories requires that the agencies be able to record and track all activity associated with each product stocked throughout its life cycle. Such information is needed to monitor activity affecting the stockpiles and make timely decisions about adjusting the composition and stock levels of the inventory as well as ordering replacements for expiring supplies. Each agency is in the process of replacing its current system with one that is expected to be able to track medical supplies from the time an order is placed until the item is consumed or otherwise disposed of. Until these upgrades are complete, information relating to order, receipt, removal, destruction, and cost of supplies is not readily available to the responsible agencies.

CDC has defined its requirements for inventory software and recently completed a review of vendor proposals. CDC's goal is to have the new system in place by April 2001. CDC's requirements include the capability to track inventory throughout each item's life cycle. Since automated information about the NPS will be kept on a variety of independent computer systems, CDC recognizes the need for its system to interface with those of its partners, and to continually track the overall status, activity, and cost of supplies. Because OEP's and CDC's system needs are similar, OEP expects to rely on the results of CDC's review of system capabilities and vendor proposals and use the same system as that selected by CDC.

The Marine Corps has developed a new inventory management system, the ATLAS II +, that it expects to implement at CBIRF by June 2001. In response to our October 1999 report, CBIRF implemented an interim inventory system in September 2000, which is capable of tracking inventory quantities, expiration dates and lot numbers, pending transition to the new

system. In addition to these capabilities, CBIRF expects its new system to be able to report whether items are on order, whether items ordered have been received, and whether items are pending shelf-life extension or waiting to be destroyed.

Rotation Policies and Practices at CBIRF and CDC Need Improvement

We previously reported that the responsible agencies' inventories included items that had expired but not been replaced and recommended that they properly rotate supplies. For example, we found that OEP had 2,000 amyl nitrite inhalants on hand which had expired 8 months prior to our 1999 visit. In response to our report, we found that all responsible agencies have developed policies and procedures related to rotating stock in their inventories. However, in some cases, planned approaches were not completely implemented.

Proper rotation entails replacing pharmaceuticals and medical supplies that have expired or are close to their expiration dates with current stock. Agency policies require expired items to be segregated and destroyed, redistributed, or put into the shelf-life extension program discussed earlier. If expired items are not appropriately removed and replaced, there is an increased risk of ineffective items being deployed, an adequate supply of effective items being unavailable, or contemplated cost savings not being realized.

During our October 2000 counts at CBIRF, we found that 161 expired pharmaceutical and medical supplies, including 146 controlled substances, were on hand. Among the expired controlled substances that had not been replaced were morphine sulfate, acetaminophen and codeine phosphate, and midazolam. The senior member of the CBIRF controlled substances inventory board told us that, prior to our October 2000 count, he had informed the CO that the inventory contained expired controlled substances and requested the CO's approval to destroy the items. He subsequently informed us that CBIRF had destroyed the expired controlled substances on December 20, 2000. However, as of January 2001, CBIRF had not replaced the expired items with current stock in sufficient quantities to meet the minimum stock levels determined by the CO's medical allowance list. According to CBIRF officials, a decision on whether to replace these expired items is pending and will be made once the MARCORSYSCOM provides program funds and the fielding plan for the CBIRF specific AMAL.

Although CDC's inventory was too new for any of its items to have expired, it had not finalized agreements with a private sector partner to implement a

stock rotation method designed to rotate soon-to-expire pharmaceuticals into the commercial marketplace and replace them with fresh stock.

In December 1999, CDC developed a unique concept for medical materiel management, termed “rotation-in-place.” CDC found that given the demand in the commercial market place for certain pharmaceutical items held by the program, NPS materiel could be more economically maintained by partnering with a pharmaceutical wholesale company. Under the partnership arrangement, the wholesaler could sell certain pharmaceuticals to hospitals and other customers before the items reached their expiration dates and replace these items with fresh stock. Thus, it would be unnecessary to hold the CDC stock until expiration, dispose of it, and replace the disposed items at full cost. This approach would result in significant cost savings that could be funneled back into the program. We were told by CDC officials that the wholesale company requires the items be returned for redistribution not less than 6 months prior to the expiration date to allow it to redistribute the supplies to its other customers with a 6-month minimum shelf life remaining on the items. CDC adopted a 12 month “trigger” date to ensure that items will be flagged and rotated in time to meet the wholesale company’s 6 month requirement.

CDC is continuing to negotiate with the wholesaler to rotate the items. If an agreement is not finalized so that supplies can be redistributed by June 2001, CDC could lose the opportunity for cost savings for approximately \$4.3 million of CDC’s inventory, which will expire by December 2001. Without finalized agreements in place, the expiring medical materiel may have to be replaced at full cost and the expired items destroyed.

Conclusion

Since our last report, the responsible agencies have significantly improved accountability over the medical supplies designated to treat victims of chemical or biological terrorism. However, ensuring that supplies are current, accounted for and readily available for use is dependent in large part on successful collaboration with other entities. Until CDC and OEP formalize certain ad hoc arrangements with other entities covering the storage, management, stock rotation and transporting of supplies, they will face the risk that, should a chemical or biological incident occur, the appropriate supplies will not be available when needed. Also, unless the agencies’ inventory requirements lists are up-to-date and reflective of their own identified needs, the agencies are limited in assuring that they have the supplies needed to fulfill their mission.

Recommendations for Executive Action

To minimize risks associated with partnering with private-sector companies and other entities in managing the National Pharmaceutical Stockpile, we recommend that the Secretary of Health and Human Services require the Director of the Centers for Disease Control and Prevention to

- execute written agreements as soon as possible with all CDC's partners covering the storage, management, stock rotation and transporting of medical supplies designated for treatment of biological or chemical terrorism victims;
- issue written guidance on security to private warehouses that store stockpiles, on such issues as granting access to the wholesale distributor for stock rotation; and
- to the extent practical, install proper fencing prior to placing inventories at storage locations.

To improve accountability over medical supplies in its inventory, we recommend that the Secretary of Health and Human Services require the Director of the Office of Emergency Preparedness to

- finalize, approve, and issue an inventory requirements list;
- improve physical security at its central location to comply with DEA regulations, or move the supplies as soon as possible to a location that meets these requirements;
- issue a written policy on the frequency of inventory counts and acceptable discrepancy rates;
- finalize and implement approved national and local operating plans addressing VA's responsibilities for the procurement, storage, management, and deployment of OEP's stockpiles; and
- train VA personnel and conduct periodic quality control reviews to ensure that national and local operating plans are followed.

To ensure the effectiveness of medical supplies in its inventory, we recommend that the Secretary of Health and Human Services require the Director of the Office of Emergency Preparedness to

- immediately contact FDA or the pharmaceutical and medical supply manufacturers of items stored at its central location to determine the impact of items exposed to extreme temperatures;
- replace those items deemed no longer usable; and
- either add environmental controls to the current location or move the supplies as soon as possible to a climate controlled space.

To ensure that medical supplies on hand reflect those identified as being needed to respond to a chemical or biological terrorism incident, we recommend that the Marine Corps Systems Command program funding and complete the fielding plan for the CBIRF specific authorized medical allowance list and that the Commandant of the Marine Corps require the Commanding Officer of the Chemical Biological Incident Response Force to

- adjust its stock levels to conform with the authorized medical allowance list and
- remove expired items from its stock and replace them with current pharmaceutical and medical supplies.

Agency Comments

We obtained written comments on a draft of this report from the Departments of Health and Human Services, Veterans Affairs, and Defense. The agencies concurred with the overall conclusion of the report and 12 of 13 recommendations. However, in several instances where they concurred with the recommendations, they took exception to the related risk that we noted. The individual agencies' responses related to the 13 recommendations are summarized below, and are reprinted in their entirety in appendixes II through IV.

HHS concurred with our recommendation that CDC finalize written agreements with its partners covering the storage, management, stock rotation and transporting of medical supplies. In its response, HHS stated that CDC has accelerated the establishment of final contractual agreements and standard operating procedures for each of its NPSP partners and, since the end of our fieldwork, has finalized some of those agreements. However, HHS did not agree that mission critical activities could be compromised by not having written agreements in place. HHS explained that it proceeded with the placement of the 12-hour push packages prior to executing final agreements in order to make the NPSP response available as soon as it was technically feasible. The NPSP is relying on existing contractual agreements between VA and its commercial partners while it finalizes agreements with these same partners. While these existing agreements are designed to address VA's hospital supply needs, they do not address key responsibilities, requirements, and control activities specific to the NPSP. We recognize the need to position the stockpiles for rapid deployment as soon as possible. However, we continue to believe that without final written agreements specifying key responsibilities of all parties, mission critical activities may not be carried out as contemplated.

HHS also concurred with our recommendation that CDC issue written guidance on security to private warehouses that store stockpiles, covering such issues as granting access to the wholesale distributor for stock rotation. HHS noted that it is in the process of updating its existing standard operating procedures to include information regarding controlled access to the NPSP inventory, key responsibilities for stock rotation, and guidelines for rotation of stock. However, HHS did not agree that the lack of such guidance increased the risk of unauthorized entry or failure to rotate inventory in a consistent and timely manner, because the private warehouses have their own security procedures in place. While we did not find any evidence that the integrity of the stockpiles had been compromised, or that stock rotations did not occur in a timely manner, we believe that written guidance is essential to reducing the risk of misunderstandings between CDC and its partners regarding security and rotation requirements. The actions HHS described that CDC is currently taking should address the risks noted in our report by ensuring that security and other procedures specific to the NPSP are carried out.

HHS did not concur with our recommendation that CDC install fencing prior to placing inventories at storage locations, because it believes that there was no risk of theft during the initial months of the 12-hour push package placements. CDC stated that it did not intend for the installation of fencing to be a theft deterrent, but rather to serve as means of segregating CDC supplies from assets belonging to others sharing adjacent storage space. The NPSP standard operating procedures highlight the importance of protecting and securing the pharmaceutical supplies by requiring that access to the assets be limited by chain link fencing and lock-secured gates. Further, the operating procedures state that the storage facility must (1) specify the employees who can access the area, (2) have a system for identifying employees with access to the assets, (3) have a process in place to ensure that only those specified employees gain access to the area, and (4) enforce its rules of access with rigor. While we agree that the storage facilities have their own security procedures in place, we continue to believe that fencing provides the added benefit of limiting access to only authorized individuals. However, we agree that theft is not the primary risk, and we have modified our recommendation as follows, "To the extent practical, install proper fencing prior to placing inventories at storage locations."

HHS agreed with all six of our recommendations regarding improving accountability over OEP's medical supplies and ensuring their effectiveness. In its response, HHS described several actions it had taken to

address our recommendations as follows. OEP approved an updated inventory requirements list on February 27, 2001. Further, national and local operating plans were approved and are being transmitted to VA. Also, OEP has taken steps to provide training to VA personnel and has conducted periodic quality control reviews. OEP has assessed the pharmaceuticals at the central location and, based on its findings, will continue to store them at this site until the supplies are moved to a new location in April. At that time, all temperature sensitive items will be replaced. In addition, OEP has directed VA to conduct a physical inventory of supplies stored at each location annually. While we did not provide OEP with a suggested tolerable inventory discrepancy rate, as noted in its response, we commend OEP for establishing a zero tolerable error rate for controlled substances and a 3- to 5-percent error rate for other items.

Although we did not address recommendations to VA in this report, the department provided comments detailing actions that it is taking in support of the NPSP and the management of OEP's inventory of medical supplies used to combat terrorism. VA acknowledges OEP's new inventory requirements list and will adjust the inventories to comply with that list in June 2001. Also, VA will augment OEP's final operating plans with site-specific plans and will assist OEP in scheduling staff to receive related training.

DOD generally concurred with both of our recommendations to adjust its stock levels to conform to the CBIRF specific authorized medical allowance list and to remove expired items from stock and replace them with current pharmaceutical and medical supplies. The Marine Corps is in the process of programming funding and ordering supplies to augment CBIRF's existing inventory of medical supplies to conform to the AMAL. Further, CBIRF will segregate expired materiel from serviceable stock and will dispose of expired materiel not included in the DOD/FDA shelf-life extension program. DOD also emphasized the fundamental differences between the purpose of its medical supplies and those of CDC and OEP. In response, we added further clarification to the background section of our report.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we will not distribute it until 30 days after its date. At that time, we will send copies to the Honorable Dennis J. Kucinich, Ranking Minority Member of your Subcommittee; Senator Fred Thompson, Chairman, and Senator Joseph I. Lieberman, Ranking Member, Senate

Governmental Affairs Committee; Representative Dan Burton, Chairman, and Representative Henry A. Waxman, Ranking Minority Member, House Governmental Reform Committee; the Honorable Donald H. Rumsfeld, Secretary of Defense; the Honorable Tommy Thompson, Secretary of Health and Human Services; the Honorable Anthony J. Principi, Secretary of Veterans Affairs; the Honorable Mitchell E. Daniels, Jr., Director of the Office of Management and Budget; and other interested parties. We will also make copies available to others upon request.

Please contact me at (202) 512-9508 or Alana Stanfield, Assistant Director, at (202) 512-3197 or by e-mail at calboml@gao.gov or stanfielda@gao.gov if you have any questions. Other major contributors to this report are listed in appendix V.

Sincerely yours,

A handwritten signature in black ink, reading "Linda Calbom". The signature is fluid and cursive, with the first name "Linda" and last name "Calbom" clearly distinguishable.

Linda M. Calbom
Director, Financial Management
and Assurance

Objective, Scope, and Methodology

Our objective was to determine the status of the corrective actions that OEP, VA, CDC, and CBIRF had taken to address our prior recommendations for improving management controls over medical supplies designated to treat victims of chemical and biological terrorism.

To determine whether these agencies had conducted risk assessments and organized program activities to mitigate risks, we obtained and reviewed each agency's risk assessment to determine its congruency with mission objectives as well as any actual or planned control activities to mitigate identified risks.

To determine whether the agencies had arranged for periodic inventories, we (1) held discussions with agency officials to understand their inventory methodologies, (2) reviewed policies, procedures, and actions implemented to perform periodic independent inventories, (3) examined evidence that agencies had performed periodic inventories, and (4) assessed agencies' follow-up actions for adequacy.

To assess the accuracy and currency of recorded medical supply data, we performed a 100-percent count of the CBIRF medical supplies with CBIRF assistance and observed and participated in counts of the CDC and OEP medical supplies with CDC, OEP, and VA officials. We then compared the count results to inventory system data to identify discrepancies in recorded quantities, expiration dates, and lot numbers. We calculated the discrepancy rate by dividing the number of discrepancies we found by the total number of recorded on-hand medical supply items.

Where available, we also compared on-hand pharmaceutical and medical supplies to management's inventory requirements lists to determine whether agencies had the recommended and approved type and quantity of supplies on-hand to effectively carry out their missions.

To determine whether agencies had implemented inventory tracking systems that retained complete documentation over the life cycle of the medical supplies, we interviewed agency officials to understand their current inventory tracking systems' capability to record, monitor, and account for on-hand medical supplies, and observed the systems' output data. We also gained an understanding of the current inventory-tracking systems' general controls and assessed them for adequacy.

To determine whether agencies had acted to properly replace expired or about to expire items with current stock (rotate supplies), we

(1) interviewed agency officials, (2) reviewed policies and procedures for rotating supplies, (3) assessed agencies' inventory tracking systems' capability to track medical supplies through their life cycle, (4) observed rotations at OEP sites, and (5) analyzed inventory reports to determine whether expired items had been timely rotated or scheduled for rotation. We also reviewed management controls for expired controlled substances that are being held in storage at VA, pending FDA approval of OEP's shelf life extension program, including performing a 100-percent count of controlled substances on hand and reconciliation with system data.

To determine the additional actions OEP, VA, CDC, and CBIRF need to take to enhance their management controls, we gained an understanding of current management controls via inquiries, observations, and inspections and compared them to the criteria in our *Standards for Internal Control in the Federal Government* (GAO/AIMD-00-21.3.1, November 1999) and *Internal Control Management and Evaluation Tool* (GAO/AIMD Exposure Draft, October 2000). We also considered criteria in the Office of Management and Budget Circular A-123, *Management Accountability and Control*, revised June 21, 1995; 31 U.S.C. 3512 (the Federal Managers' Financial Integrity Act of 1982); and the *Federal Financial Management Systems Requirements* of the Joint Financial Management Improvement Program. As part of our work, we also reviewed certain presidential directives and the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, to determine U.S. policy on chemical and biological terrorism.

The scope of our review did not include an analysis of (1) how these stockpiles fit into national counterterrorism plans, (2) the concept of operations for the use of these stockpiles, or (3) whether these stockpiles contain the appropriate medications. We did not examine the stockpiles and inventories held by U.S. military forces and managed by the Defense Logistics Agency for military purposes. We also excluded from our review controls over stockpiles that are maintained by Metropolitan Response System Teams in several U.S. cities for chemical and biological terrorist incidents. We did not review controls over the inventory of smallpox vaccine, since no weaknesses were identified in our prior report.

We conducted our review from August 2000 through December 2000 in accordance with generally accepted government auditing standards.

Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAR 15 2001

Ms. Linda M. Calbom
Director
Financial Management & Assurance
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Calbom:

Enclosed are the Department's comments on your draft report, "Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script, reading "Michael F. Mangano", is written over the typed name.

Michael F. Mangano
Acting Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Appendix II
Comments From the Department of Health
and Human Services

Comments of the Department of Health and Human Services on the General Accounting Office's Draft Report, "Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement"

General Comments

The Department of Health and Human Services (Department) appreciates the opportunity to comment on the U.S. General Accounting Office's (GAO) follow-up draft report on combating terrorism (GAO-01-463). We are pleased that GAO recognizes the substantial effort that the Department has made to improve the management of our pharmaceutical stockpiles since the last report. We also continue to consider GAO's findings valuable, and are already in the process of addressing the recommendations; however, we believe certain issues highlighted in the draft report require clarification.

The Department is working diligently to address GAO's recommendations. Through the Centers for Disease Control and Prevention's (CDC) National Pharmaceutical Stockpile (NPS) program and through the Office of Emergency Preparedness' national pharmaceutical caches, the Department will continue to ensure the availability and rapid deployment of life saving pharmaceuticals and medical materiel to the Nation in the event of a biological or chemical terrorism incident.

In their statements about the CDC stockpiles, GAO recommended executing written agreements [including standard operating procedures (SOPs) and finalized contractual agreements] with all NPS program partners covering storage, management, stock rotation and transportation. The GAO expressed concern that, without such agreements in place, there is an increased risk that mission critical activities may not be carried out.

While the Department agrees with the need for final written agreements, we do not agree that mission critical activities may be compromised in the absence of such agreements.

- The CDC has interim SOPs and contractual agreements that are currently in place. While we wholeheartedly agree with the need to accelerate the establishment of final contractual agreements and outstanding SOPs for each NPS program partner, we would like to explain the reasoning behind CDC's decision to proceed with placement of medical materiel before final written agreements are executed. The draft report did not address the potential risk that faced the Nation prior to the placement of 12-hour push packages and the need for an NPS program response to be available as soon as was technically feasible.
- The NPS program used existing contractual agreements between the Department of Veterans' Affairs (VA) and commercial partners before purchasing or placing assets at storage locations.
- The CDC selected its program partners and storage location sites based on their known good business practices, security measures, and procedural methods associated with handling large pharmaceutical and medical materiel inventories. These strengths provide

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and Human Services

the NPS program with contingent methods to ensure the integrity of inventory and the ability of the program to maintain readiness. At this time, some of CDC's written contractual agreements with NPS program partners are finalized and some are undergoing legal evaluation. The CDC will finalize all outstanding SOPs. Once completed, the SOPs and written contractual agreements will serve to codify procedures already in place.

In their second recommendation about CDC's program, GAO recommended that CDC issue written guidance on security (that is, access to storage sites for rotation purposes) to two private warehouse storage facilities. The GAO expressed concern that without adequate SOPs or a final written contractual agreement in place to guide access and security control activities, there is increased risk of unauthorized access to NPS program inventory, and that inventory may not be rotated in a consistent and timely manner.

The Department agrees that written guidance is necessary, but does not agree that lack of final written guidance increases the risk of unauthorized entry or failure to rotate inventory in a consistent and timely manner.

- Each NPS program storage partner has procedures in place to govern admittance of only authorized individuals to their facilities.
- The CDC is in the process of updating their existing SOP to ensure it includes information regarding controlled access to NPS program inventory (particularly at private warehouses), key responsibilities for stock rotation, and guidelines for rotation of stock.
- The CDC NPS program utilizes a stringent regimen of regularly scheduled quality assurance and quality control inventory checks and unannounced visits in order to assure that NPS program inventory is accounted for and secure.
- The final written contractual agreement with a wholesale distributor has been completed.
- Working without a final written agreement specific to 12-hour push packages has not precluded the timely and consistent rotation of NPS program inventory.

In their third recommendation, GAO recommended installation of proper fencing as a theft deterrent at selected storage sites prior to placement of inventory.

The Department does not agree with this recommendation.

- The CDC believes there was no risk of theft of materiel during the initial months of 12-hour push package placement, as the commercial facilities chosen to store 12-hour push packages are bonded, licensed by the Food and Drug Administration (FDA), or approved by the Drug Enforcement Administration (DEA) to operate under strict security controls. All aspects of existing operations are designed to ensure the physical integrity of pharmaceuticals and eliminate all risks of loss and theft. Fencing was never intended to be installed as a theft deterrent, rather, it was installed to serve as a demarcation of

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NPS program assets within a larger warehouse (CDC NPS Program Standards and SOPs for Managing NPS Program Assets at Storage Sites).

- The regularly scheduled quality assurance and quality control monitoring of NPS program inventory, unannounced visits to each location, and other redundancies built into the NPS program further contribute to elimination of the risk of loss and theft.
- Fencing that CDC has erected does add an additional level of security at nominal expense, but is truly irrelevant compared to the multilayered security design existing at each site.

In the first set of recommendations concerning the stockpiles administered by the OEP to improve accountability over medical supplies in inventories, GAO recommended that the Department: finalize, approve and issue an inventory requirements list; improve physical security at its central location to comply with DEA regulations, or move the supplies as soon as possible to a location that meets these requirements; issue a written policy on the frequency of inventory counts and acceptable discrepancy rates; finalize and implement approved national and local operating plans addressing VA's responsibilities for procurement, storage, management, and deployment of OEP's stockpiles; and provide training to VA personnel and conduct periodic quality control reviews to ensure that national and local operating plans are followed.

The Department is already addressing these items.

- The OEP established a cache requirement list on April 14, 2000, which reflected product increases in the National Disaster Medical System and Weapons of Mass Destruction cache. In addition, an updated product requirement list was approved on February 27, 2001.
- The OEP identified security issues at the stockpiles' central location, and has been working with the VA to identify a new location that would meet all security and controlled temperature requirements. The VA has identified a new location for the central cache. The OEP is in the process of adding intrusion alarms, motion detectors, access and temperature monitoring systems to the cache cages (at all locations). The OEP expects the central cache to be moved to the new location during April 2001.
- During a March 2000 hearing before the House Governmental Affairs Committee, the VA stated that four complete inventories would be completed during calendar year 2000. In fact, all of the inventories have been done. For 2001, it was decided (during a December 2000 OEP and VA cache teleconference that each cache will be completely inventoried once each year. In addition, each tote that is opened for a product rotation will be inventoried at that time. If inventory results indicate problems, or any irregularities are found, more frequent inventories will be performed. For discrepancy rates, OEP is following GAO's suggested tolerable inventory discrepancy rate levels--a zero tolerable error rate for controlled substances because of the higher risks associated with them, and an error rate of between 3 and 5 percent for items that are low-cost and easily replaced. In November, 2000, the inventory discrepancy rates for the caches produced results of 0.3

percent to 0.85 percent. There were no errors for controlled substances.

- National and local operating plans have been approved, notification of which is being officially transmitted to the VA.
- The OEP, their logistical contractor, and the VA emergency pharmacy staff have provided training to VA staff working on security, cache management, and hospital administration. In addition, the OEP has provided operational plan management at each location. Periodic quality control reviews occur during monthly teleconference calls, and during on-site audits of the cache inventories and cache management.

In the second set of recommendations to the Department to ensure the effectiveness of medical supplies in their inventory, GAO recommended that FDA or the pharmaceutical and medical supply manufacturers be contacted to determine the impact of items exposed to extreme temperatures at the central location; replace those items deemed no longer usable; and either add environmental controls to the current location (central) or move the supplies as soon as possible to a climate controlled space.

The Department agrees.

- The OEP has assessed the pharmaceuticals stored at the central location and found that Diazepam, a major component of the cache, has a storage condition that states "Short excursions to higher temperatures may be permitted." In addition, when FDA's Office of Generic Drugs grants a 2-year shelf-life to a pharmaceutical product, the drug may be subject to 104° Fahrenheit for 90 days at 75 percent relative humidity. Based on these findings, the OEP will allow these pharmaceuticals to be stored in the central cache until a new location is completed, at which time they will be replaced (that is, within several months).
- The OEP is in the process of adding intrusion alarms, motion detectors, access and temperature monitoring systems to the cache cages at all locations, in addition to the building alarms. The OEP has received bids from 3 vendors and will soon start installation. The new central cache location will have a building alarm and monitors on the cache cage.
- The OEP will replace all temperature sensitive products when the central cache is moved to a new location in April 2001.

Technical Comments

Several additional items in the draft report require clarification:

- The Department is pleased that GAO's draft report recognizes CDC's extensive effort to develop the NPS "rotation in place" program in order to prevent unnecessary waste due to expiring materiel. However, the draft report is not accurate with regard to the rotation timetable associated with this concept. The draft report stated that the wholesale

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Comments From the Department of Health
and Human Services

distributor requires at least 12 months of shelf life for resale. In fact, the wholesale distributor requires only 6 months of shelf life for resale. The CDC has adopted a 12-month "trigger" date in order to ensure that all items will be flagged and rotated in time to meet the 6-month expiration date needed for resale. The majority of the inventory totaling \$4.3 million which the draft report identified as being "at risk" has already been rotated. The CDC had until June 2001 to initiate rotation of that stock, not December 2000 as stated in the draft report. The CDC is in the process of updating the existing SOP in order to ensure it includes key responsibilities for stock rotation, and guidelines for rotation of stock specific to the 12-hour push packages. The NPS program operates under existing contractual agreements between the VA and commercial partners.

- In the draft report, there are several references that state other entities manage NPS program inventory. This is not accurate. While CDC has several public and private sector partners to help with NPS program functions, CDC retains the management of all aspects of the NPS program including NPS program inventory.
- The CDC has selected and awarded a contract for a new inventory management system as of March 1, 2001. The CDC will also provide access to and use of the system to OEP.
- Twelve-hour push packages will be delivered to the scene of a terrorism event within 12 hours of a Federal decision to deploy assets, not within 12 hours of notification of an incident, as stated in the draft report.

The draft report concluded that until CDC has formal written agreements in place governing storage, management, stock rotation, and transporting of supplies, there is a risk that appropriate supplies will not be available, or that expired or otherwise ineffectual supplies would be delivered to the scene of a terrorist incident. We believe that this statement conflicts with positive statements made in reference to the CDC in the body of the draft report. For example, the draft report noted that CDC followed its internal guidelines for establishing the composition and stock levels of medical supplies thereby ensuring that appropriate medical materiel would be available in the event of a biological or chemical terrorism event. In addition, the draft report stated that no expired items were found in NPS program inventory, nor were there any unresolved discrepancies between NPS program inventory and management system data.

Comments From the Department of Veterans Affairs



THE SECRETARY OF VETERANS AFFAIRS

WASHINGTON

MAR 15 2001

Ms. Linda M. Calbom
Director, Financial Management and Assurance
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Calbom:

This responds to your draft report, **COMBATING TERRORISM: Accountability Over Medical Supplies Needs Further Improvement** (GAO-01-463). I appreciate that the General Accounting Office (GAO) recognizes recent efforts the Department of Veterans Affairs (VA) has taken to strengthen its internal controls over the medical supplies we stock in support of the National Pharmaceutical Stockpile Program (NPSP) and the National Disaster Medical System – Weapons of Mass Destruction (NDMS-WMD) cache.

Although your recommendations are directed to the Centers for Disease Control (CDC), the Office of Emergency Preparedness (OEP), and the U.S. Marine Corps Chemical Biological Incident Response Force (CBIRF), I am eager to convey recent VA actions that will assure our supplies are current, accounted for, and readily available to respond effectively to chemical or biological terrorist incidents. While the OEP has yet to finalize our jointly drafted national operating plan, VA facilities where caches are located continue to update their local plans. Also, VA's Emergency Management Strategic Healthcare Group has updated its interim operating procedures that will guide VA response to cache activation, pending OEP's signing of the national plan.

The enclosure details actions the Department is taking in support of the NPSP. I take seriously VA's role in this program and pledge to you we will do whatever is possible to meet our responsibilities to assure VA-managed pharmaceutical stockpiles are available to American citizens injured as the result of a chemical or biological terrorist incident.

Thank you for the opportunity to comment on your draft report.

Sincerely yours,

Handwritten signature of Anthony J. Principi in black ink.
Anthony J. Principi

Enclosure

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS TO
GAO DRAFT REPORT, **COMBATING TERRORISM:**
Accountability Over Medical Supplies Needs Further Improvement
(GAO-01-463)

Although the General Accounting Office (GAO) did not direct its recommendations to the Department of Veterans Affairs (VA), we offer these comments to support them.

To improve accountability over medical supplies in its inventory, GAO recommends that the Secretary of Health and Human Services (HHS) require the Director of the Office of Emergency Preparedness (OEP) to

- **Finalize, approve and issue an inventory requirements list,**

On February 27, 2001, the Office of Emergency Preparedness (OEP) provided VA a signed inventory requirements list. OEP requested that the cache inventories be adjusted to comply with that list at the next site visit, due in June 2001. VA shall honor that request.

- **Improve physical security at its central location to comply with Drug Enforcement Administration (DEA) regulations, or move the supplies as soon as possible to a location that meets these requirements,**

The Central cache is scheduled to move to a new VA-controlled storage location in April 2001. This new location will adhere to all VA and DEA guidelines regarding proper security for storage of the cache. Additionally, VA has researched options for installation of electronic access control devices at all storage sites. OEP is reviewing VA's request for funding of this proposal.

- **Issue a written policy on the frequency of inventory counts and acceptable discrepancy rates,**

In December 2000, OEP clarified the inventory frequency for calendar year 2001 during the monthly National Medical Response Team Cache Teleconference meeting. The minutes of the call recorded this information. If VA opens a cache for product rotation, we will inventory all portions of the cache. Additionally, VA will conduct one complete inventory during the calendar year. VA is prepared to assist OEP in establishing an acceptable discrepancy rate; we have proposed a "mission readiness" concept as a more suitable unit of measure.

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS TO
GAO DRAFT REPORT, **COMBATING TERRORISM:**
Accountability Over Medical Supplies Needs Further Improvement
(GAO-01-463)
(Continued)

- **Finalize and implement approved national and local operating plans addressing VA's responsibilities for the procurement, storage, management, and deployment of OEP's stockpiles, and**

The OEP/VA-developed draft operating plans have been approved and are at OEP awaiting signature. Upon OEP's finalization, each site will conduct training on the plan. While local VA sites have already developed draft operating plans, none will be implemented until VA obtains the signed approved plans from OEP.

- **Provide training to VA personnel and conduct periodic quality control reviews to ensure that national and local operating plans are followed.**

After OEP determines the training content and schedule, VA will assist in scheduling staff to receive the training.

To ensure the effectiveness of medical supplies in its inventory, GAO recommends that the Secretary of HHS require the Director of OEP to

- **Immediately contact the Food and Drug Administration (FDA) or the pharmaceutical and medical supply manufacturers of items stored at its Central location to determine the impact of items exposed to extreme temperatures,**

There are 142 unique items in the cache, 97 of which are not labeled with a temperature range. We believe manufacturers are unlikely to release information to support viability of the products. However, VA will comply with guidance that OEP provides regarding the disposition of the products in this cache.

- **Replace those items deemed no longer usable, and**

VA will replace any items that OEP deems no longer usable.

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS TO
GAO DRAFT REPORT, **COMBATING TERRORISM:**
Accountability Over Medical Supplies Needs Further Improvement
(GAO-01-463)
(Continued)

- **Either add environmental controls to the current location, or move the supplies as soon as possible to a climate controlled space.**

VA will move the Central cache to a new, secure, temperature-controlled storage location as soon as the storage cage is constructed. This is pending a General Services Administration approval of a Request for Work Authorization.

Additional Comments:

GAO raises two issues that did not result in a recommendation; nevertheless, VA offers the following comments:

1. Current tracking systems do not record inventory activity over the life cycle of the supplies: OEP has notified VA that the inventory management system that the Centers for Disease Control (CDC) selected for use in the National Pharmaceutical Stockpile Program will also be used for the National Disaster Management System/Weapons of Mass Destruction (NDMS/WMD) cache program. The procurement process for this system is underway. CDC will implement and verify the system for at least 6 weeks before it will be made available to OEP/VA for use. Once the NDMS/WMD cache data have been transferred to the new system, VA will inventory at each storage site to verify the data.
2. Periodic inventories reduced discrepancy rates: VA has corrected the discrepancies in the expired Diazepam inventory. VA will reconcile records with each adjustment in the stock level. We will also conduct periodic inventories to ensure accuracy is maintained.

Comments From the Department of Defense



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000



14 MAR 2001

Ms. Linda M. Calbom
Director
Financial Management and Assurance
United States General Accounting Office
Washington, DC 20548


Dear Ms. Calbom,

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) draft report, "COMBATING TERRORISM: Accountability Over Medical Supplies Needs Further Improvement," dated March, 2001 (GAO Code 916371/OSD Case 3047).

The Department generally concurs with the recommendations regarding the maintenance of the medical supplies of the Chemical/Biological Incident Response Force (CBIRF). The Marine Corps is currently developing / revising the appropriate Authorized Medical Allowance List (AMAL), which they will then compare with on hand materiel; identify shortfalls or excesses; and develop and implement a fielding plan to correct the initial outfitting.

The Department would like to emphasize, however, that the purpose of the medical supplies managed by CBIRF is fundamentally different from that of the National Pharmaceutical Stockpile of the Department of Health and Human Services' Office of Emergency Preparedness, the Centers for Disease Control and Prevention, and the Department of Veterans Affairs. Medical material maintained by CBIRF is intended for the use of CBIRF medical personnel to provide emergency medical care and stabilization of injured CBIRF personnel and only a limited number of other casualties. A true evaluation of the accountability of medical supplies for CBIRF and these other Federal agencies could probably have been better accomplished within separate reviews.

The Department appreciates the opportunity to comment on the draft report. Detailed comments for technical correctness and accuracy have been provided separately to the GAO.


Charles L. Cragin
Acting

Enclosure: Response to GAO Draft Report



GAO DRAFT REPORT – DATED MARCH, 2001
GAO CODE 916371/GAO-01-463

“COMBATING TERRORISM: ACCOUNTABILITY OVER
MEDICAL SUPPLIES NEEDS FURTHER IMPROVEMENT”

DEPARTMENT OF DEFENSE COMMENTS
TO THE RECOMMENDATION

RECOMMENDATION: The GAO recommended that the Navy Medical Logistics Command issue the approved U.S. Marine Corps Chemical Biological Incident Response Force specific medical allowance list. (p. 30/GAO Draft Report)

DOD RESPONSE: Concur with the intent of the recommendation. Marine Corps Systems Command (MARCORSYSCOM) is the Program Manager for medical materiel under the direction of the Commander, Marine Corps Materiel Command. As the Program Manager, MARCORSYSCOM develops the component configurations for USMC Authorized Medical Allowance Lists (AMALs) to support a validated materiel/equipment requirement. The Navy Medical Logistics Command (NMLC) published the allowances via a Naval Message and through the NMLC Internet site in October 2000.

RECOMMENDATION: The GAO recommended that the Commandant of the Marine Corps require the Commanding Officer, U.S. Marine Corps Chemical Biological Incident Response Force to:

- Adjust its stock levels to conform with the Navy Medical Logistics Command’s approved U.S. Marine Corps Chemical Biological Incident Response Force specific medical allowance list, and
- Remove expired items from its stock and replace them with current pharmaceutical and medical supplies. (pp. 30-31/GAO Draft Report)

DOD RESPONSE: Concur with the intent of the recommendation. Marine Corps System Command (MARCORSYSCOM) has finalized the CBIRF AMAL line item configurations and requested establishment of a Table of Authorized Material Control Numbers (TAMCNs). MARCORSYSCOM will program funding in the Program Objectives Memorandum (POM) budget and develop/execute the fielding plan for new medical equipment. USMC will identify shortfalls and develop a fielding plan for the initial outfitting.

Expired medical materiel will be segregated from serviceable stock, but not necessarily disposed. The CO, CBIRF segregates expired medical materiel from serviceable stock. Expired materiel not in the DoD/FDA Shelf Life Extension Program (SLEP) is processed for disposal.

GAO Contact and Staff Acknowledgments

GAO Contact	Linda M. Calbom, (202) 512-9508
Acknowledgments	In addition to the contact named above Louise Beck, Cary Chappell, David Grindstaff, Bronwyn Hughes, Charles Norfleet, Alana Stanfield, McCoy Williams, and Maria Zacharias made key contributions to this report.

Appendix V
GAO Contact and Staff Acknowledgments

Glossary

Acetaminophen and
Codeine Phosphate

An over the counter pain reliever and fever reducer combined with a narcotic analgesic used to treat moderate to severe pain.

Amyl nitrite

An inhalation drug that is used as an antidote for cyanide poisoning. It is also a common recreational stimulant known as a popper.

Atropine

A cardiac drug that is also used to reverse the effects of organophosphate poisoning.

Ciprofloxacin

A drug, also known as Cipro, that is used to treat infections, including anthrax.

Controlled Substance

A substance that has a high potential for abuse, as classified by the Controlled Substances Act, title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Diazepam

A drug that is used to treat the symptoms of anxiety, convulsions, and muscle spasms. Its brand name is Valium.

Midazolam

A drug used to produce sleepiness or drowsiness and to relieve anxiety before surgery or certain procedures. It is also used to produce loss of consciousness before and during surgery.

Morphine Sulfate

A drug in the class of narcotic analgesics used to treat moderate to severe pain.

¹The pharmaceuticals listed here may have alternative uses in a chemical or biological incident. We have described their primary purpose.

Oropharyngeal Airway

A device that is inserted into an unobstructed pharynx through the mouth to provide an airway.

Related GAO Products

(as of November 30, 2000)

Combating Terrorism: Federal Response Teams Provide Varied Capabilities; Opportunities Remain to Improve Coordination (GAO-01-14, November 30, 2000).

West Nile Virus Outbreak: Lessons for Public Health Preparedness (GAO/HEHS-00-180, September 11, 2000).

Combating Terrorism: Linking Threats to Strategies and Resources (GAO/T-NSIAD-00-218, July 26, 2000).

Combating Terrorism: Comments on Bill H.R. 4210 to Manage Selected Counterterrorist Programs (GAO/T-NSIAD-00-172, May 4, 2000).

Combating Terrorism: How Five Foreign Countries Are Organized to Combat Terrorism (GAO/NSIAD-00-85, April 7, 2000).

Combating Terrorism: Issues in Managing Counterterrorist Programs (GAO/T-NSIAD-00-145, April 6, 2000).

Combating Terrorism: Chemical and Biological Medical Supplies Are Poorly Managed (GAO/T-HEHS/AIMD-00-59, March 8, 2000).

Combating Terrorism: Chemical and Biological Medical Supplies are Poorly Managed (GAO/HEHS/AIMD-00-36, October 29, 1999).

Combating Terrorism: Observations on the Threat of Chemical and Biological Terrorism (GAO/T-NSIAD-00-50, October 20, 1999).

Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attack (GAO/NSIAD-99-163, September 7, 1999).

Combating Terrorism: Observations on Growth in Federal Programs (GAO/T-NSIAD-99-181, June 9, 1999).

Combating Terrorism: Use of National Guard Response Teams Is Unclear (GAO/NSIAD-99-110, May 21, 1999).

Combating Terrorism: Issues to Be Resolved to Improve Counterterrorist Operations (GAO/NSIAD-99-135, May 13, 1999).

Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives (GAO/T-NSIAD-99-112, March 16, 1999).

Combating Terrorism: Observations on Federal Spending to Combat Terrorism (GAO/T-NSIAD/GGD-99-107, March 11, 1999).

Combating Terrorism: Opportunities to Improve Domestic Preparedness Program Focus and Efficiency (GAO/NSIAD-99-3, November 12, 1998).

Combating Terrorism: Observations on Crosscutting Issues (GAO/T-NSIAD-98-164, April 23, 1998).

Combating Terrorism: Threat and Risk Assessments Can Help Prioritize and Target Program Investments (GAO/NSIAD-98-74, April 9, 1998).

Combating Terrorism: Spending on Governmentwide Programs Requires Better Management and Coordination (GAO/NSIAD-98-39, December 1, 1997).

Combating Terrorism: Federal Agencies' Efforts to Implement National Policy and Strategy (GAO/NSIAD-97-254, September 26, 1997).

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